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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte AVRAM REUBEN GOLD

Appeal 2009-015120
Application 10/755,038
Technology Center 3700

Before TONI R. SCHEINER, ERIC GRIMES, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This appeal under 35 U.S.C. § 134 involves claims to methods of treating functional somatic syndromes. The Examiner rejected the claims as obvious.

We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

Claims 1, 5, 6, 8-12, 16, 17, 19, and 20 are pending and on appeal (App. Br. 5).[2] Claims 1 and 12, the independent claims, are representative and read as follows:

> 1. A method of treating functional somatic syndromes comprising the steps of:
>
> determining whether a patient suffers from inspiratory airflow limitation during sleep;
>
> identifying such a patient as having a functional somatic syndrome; and
>
> treating such a patient with an upper airway stabilization technique;
>
> wherein treating such a patient with an upper airway stabilization technique comprises stabilizing the airway with positive airway pressure therapy.

> 12. A method of treating functional somatic syndromes comprising the steps of:
>
> determining whether a patient suffers from inspiratory airflow limitation during sleep;
>
> identifying such a patient as having one or more symptoms of a functional somatic syndrome; and
>
> treating such a patient with an upper airway stabilization technique;
>
> wherein treating such a patient with an upper airway stabilization technique comprises stabilizing the airway with positive airway pressure therapy.

[2] Appeal Brief filed May 7, 2008.

The following rejections[3] are before us for review:

(1) Claims 1, 5, 6, 11, 12, 16, and 17, rejected under 35 U.S.C. § 103(a) as obvious over Thornton[4] and Goor[5] et al. (Ans. 5-10);

(2) Claims 8, 9, 19, and 20, rejected under 35 U.S.C. § 103(a) as obvious over Thornton, Goor, and Kowallik[6] et al. (Ans. 10-11); and

(3) Claim 10, rejected under 35 U.S.C. § 103(a) as obvious over Thornton, Goor, and Bennett[7] (Ans. 12).

OBVIOUSNESS

ISSUE

The Examiner cites Thornton as disclosing a device "for treating breathing disorders, i.e. patient suffering from obstructive sleep apnea and snoring" (Ans. 5). The Examiner also finds that "it is known in the art that symptoms are identified by medical personnel to arrive at a treatment plan to alleviate the patient's medical condition, in order to identify a diagnosis compatible with the symptoms and treatments" (*id.* at 5-6).

Thus, the Examiner reasons, "upon a physician identifying symptoms associated with a patient suffering from inspiratory airflow limitation during sleep, the physician would treat a patient with the Thornton device, and would utilize the information and knowledge from the symptoms and

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[3] The Examiner entered each of the current rejections as a new ground of rejection (*see* Ans. 3-4). Appellant acknowledged the new grounds, and explicitly "requests that the appeal be maintained and submits this Reply Brief addressing each of the new grounds of rejection" (Reply Br. 1).
[4] U.S. Patent No. 5,954,048 (filed April 16, 1997).
[5] U.S. Patent No. 6,322,515 B1 (filed June 2, 1999).
[6] U.S. Patent No. 6,752,766 B2 (filed January 28, 2002).
[7] U.S. Patent No. 5,378,686 (filed September 21, 1992).

treatment to arrive at a diagnose [sic] of functional somatic syndrome" (*id.* at 6).

The Examiner finds that Thornton "does not expressly disclose an explicit correlation between the symptoms of functional somatic syndrome and sleep apnea. However, at the time the invention was made, the correlation between the symptoms of functional somatic syndrome and sleep apnea were known," as evidenced by Goor (*id.*). Based on Goor's teachings, the Examiner finds that an ordinary artisan would understand that sleep apnea "presents a patient having airflow limitation during sleep and would present a person with un-refreshed and fragmented sleep from the repetitive instances of arousal during the sleep cycle" (*id.*).

Therefore, the Examiner concludes, an ordinary artisan would have considered it obvious to "use the device of Thornton with a method of treating the functional somatic syndrome as taught by Goor in order to treat the symptoms [of] functional somatic syndrome, such as air flow limitation during sleep" (*id.* at 7).

Appellant contends that the method of claim 1 stems from the "pioneering recognition and discovery that inspiratory airflow limitation during sleep demonstrably plays a primary role in development of the functional somatic syndromes" (Reply Br. 6). Based on this discovery, Appellant discloses and claims "treatment of inspiratory airflow limitation via an upper airway stabilization technique, like positive airway pressure therapy as one provided example, [which] 'improves the symptoms/signs associated with the functional somatic syndromes'" (*id.* (quoting Spec. [0066])). Accordingly, Appellant urges, "Appellant alone identifies a causal connection between inspiratory airflow limitation during sleep and the

functional somatic syndromes and further teaches the corrective regimen of upper airway stabilization" (*id.*).

Appellant also argues that functional somatic syndromes have specific medically recognized definitions and sets of identifying characteristics, and are "a unique class of disorders for which current medical science has been unable to identify a unifying underlying cause" (*id.* at 7). In contrast, Appellant argues, neither Thornton nor Goor mentions anything about functional somatic syndromes, nor do those references describe any type of causal connection between sleep apnea, its remedies and diagnostic methods, and functional somatic syndromes (*id.* at 7-11, 13-14).

Appellant further argues that the Examiner incorrectly identified sleep disorders, such as sleep apnea, as falling within the rubric of functional somatic syndromes (*id.* at 12). Thus, Appellant urges:

> [T]he very foundation of the reasoning present in the Examiner's Answer in support of the rejection of claim 1 is fundamentally flawed and based on an incorrect reading of Appellant's disclosure relating to a method of diagnosing sleep disorders which may stem concurrently from Appellant's work in the field of functional somatic syndromes.

(*Id.*)

Appellant concludes:

> [T]he Examiner's Answer appears to assume that a physician would not only treat a patient identified as suffering from inspiratory airflow limitations during sleep with the Thornton device, but would also utilize this information to arrive at a diagnosis of a functional somatic syndrome. Fundamentally, the Examiner's Answer makes a leap in logic that a recognized expert in the field of Sleep Medicine declares is not present. Only Appellant's disclosure provides the relationship between inspiratory airflow limitations during sleep and the functional

> somatic syndromes. This relationship is not present in either Thornton or Goor.

(*Id.* at 14; *see also* App. Br. 25 (Evidence Appendix (citing Declaration of Dr. Mark H. Sanders under 37 C.F.R. § 1.132 (executed May 16, 2007))).)

Appellant reiterates the above arguments in traversing the Examiner's obviousness rejection of claim 12 (*see* Reply Br. 15-18).

In view of the positions advanced by Appellant and the Examiner, the issue is whether the evidence of record supports the Examiner's conclusion that a person of ordinary skill in the art would have considered the methods recited in claims 1 and 12 obvious in view of Thornton and Goor.

FINDINGS OF FACT ("FF")

1. In the section entitled "Description of the Related Art," the Specification states:

> Functional somatic syndromes (FSS) may be defined as physical syndromes without an organic disease explanation, demonstrable structural changes, or established biochemical abnormalities. Thus, patients suffering from functional somatic syndromes are characterized more by symptoms, suffering, and disability than by consistently demonstrable tissue abnormalities. Functional somatic syndromes are thought to be multiaxial syndromes in which psychological factors (depression), neurological factors (increased pain sensitivity), hormonal factors (orthostatic hypotension and alterations in the hypothalamic-pituitary adrenal axis), and sleep-related factors (frequent arousal and alpha frequency intrusion into sleep) interact to produce a complex clinical presentation.

(Spec. [0005].)

2. The Specification also states:

> The functional somatic syndromes generally include: chronic fatigue syndrome, fibromyalgia, irritable bowel syndrome,

> migraine/tension headaches, and temporomandibular joint syndrome. Other examples of functional somatic syndromes are thought to include: premenstrual syndrome, multiple chemical sensitivity, sick building syndrome, repetition stress injury, side effects of silicone breast implants, Gulf War syndrome, chronic whiplash, restless leg/periodic limb movement syndrome, and like ailments.

(*Id.*)

3. The Specification further states, in the section entitled "Description of the Related Art":

> In addition to a common symptom of excessive sleepiness/fatigue, functional somatic syndromes feature other symptoms/signs such as: chronic fatigue, irritable bowel, migraine/tension headaches, temporomandibular joint pain, premenstrual pain, sleep-onset insomnia, sleep maintenance insomnia, unrefreshing sleep, EEG evidence of sleep fragmentation, bruxism, muscle pain, muscle tenderness, gastroesophageal reflux (i.e., heartburn), abdominal pain, abdominal urgency, diarrhea, depression, orthostatic syncope, and alpha-delta sleep.

(*Id.* at [0007].)

4. The May 16, 2007 Declaration of Mark H. Sanders ("Declaration") states that paragraph [0005] of the Specification "correctly identifies a medical literature-identified listing of functional somatic syndromes" including the syndromes listed in FF 2, above (Declaration 2, ¶ 5).

5. In addition to describing treatments for functional somatic syndromes, Appellant's Specification discloses methods for diagnosing sleep disorders:

> In another embodiment, the present invention is a method of diagnosing a sleep disorder. The diagnosing method generally includes determining whether a patient suffers from one or more symptoms of a functional somatic syndrome, and diagnosing such a patient as having sleep-disordered breathing.

> The diagnosed patient may be treated with an airway stabilization technique in accordance with the present invention.

(Spec. [0014].)

6. The Specification then states that the "patient may be diagnosed as having obstructive sleep apnea/hypopnea (OSA/H) or upper airway resistance syndrome (UARS) based on whether alpha-delta sleep is present in the patient's sleep cycle . . . and may then be treated with an airway stabilization technique" (*id.* at [0015]).

7. The Specification then states that the "airway stabilization technique may include stabilizing the patient's airway with a mechanical stabilization" (*id.* at [0016]).

8. The Specification then states:

> The diagnosing step of the method may be based on one or more symptoms of a functional somatic syndrome, such as chronic fatigue, irritable bowel, migraine headaches, tension headaches, temporomandibular joint pain, premenstrual pain, sleep-onset insomnia, sleep maintenance insomnia, unrefreshing sleep, EEG evidence of sleep fragmentation, bruxism, muscle pain, muscle tenderness, heartburn, abdominal pain, abdominal urgency, diarrhea, depression, orthostatic syncope, and alpha-delta sleep.

(*Id.* at [0017].)

9. As background to its invention, Thornton discloses:

> Many people experience breathing problems, which may result in difficulty sleeping, in snoring, or in other more serious conditions such as obstructive sleep apnea. One treatment for such breathing disorders involves the use of devices inserted into a user's mouth for extending the user's lower jaw forward. These devices open the breathing passageway more fully to allow easier breathing through the nose and mouth.

(Thornton, col. 2, ll. 14-21.)

10. Thornton discloses that the "device and method of the present invention reduce or eliminate disadvantages and problems associated with devices and methods for improving breathing" (*id.* at col. 2, ll. 42-44).

11. Thornton discloses that its invention "increases the opening of the user's breathing passageway to increase effectiveness of treatments for breathing disorders such as obstructive sleep apnea, while remaining more comfortable for the user" (*id.* at col. 2, l. 65 through col. 3, l. 2).

12. Thornton discloses that "another important technical advantage of the present invention includes providing a removable connector for coupling the device to a face mask that may be used in cooperation with the device and a gas supply system for treatment of snoring, obstructive sleep apnea, or other breathing disorders" (*id.* at col. 3, ll. 5-10).

13. In particular, Thornton discloses that its device "may be adapted for use in connection with a face mask . . . and a continuous positive air pressure (CPAP) system . . . for supplying a gas to [the] face mask" (*id.* at col. 4, ll. 44-46).

14. Goor discloses a method of "monitoring changes in the peripheral arterial vasoconstriction in reaction to such state or condition, particularly those related to cardiopulmonary distress and blood pressure in order to detect or monitor the physiological state or medical condition of the patient" (Goor, col. 1, ll. 25-29).

15. Goor discloses that while its invention "relates to detecting and monitoring numerous physiological states and medical conditions, four particular examples generally related to cardiopulmonary distress and blood pressure are provided herein; namely, myocardial ischemia, sleep staging,

sleep apnea syndrome, and continuous blood pressure monitoring" (*id.* at col. 1, ll. 36-41).

16. Goor discloses:

> Sleep apnea syndrome is one of the most common and serious sleep disorders. It is characterized by repetitive episodes of upper airway collapse during sleep resulting in interruption of airflow despite persistent respiratory effort. Obstructive apneas are typically associated with progressively increasing asphyxia until termination by a brief arousal from sleep and restoration of upper airway patency.

(*Id.* at col. 6, ll. 51-57.)

17. Goor discloses:

> To diagnose sleep apnea syndrome, usually simultaneous recordings are made on a multi-channel recorder consisting of an electroencephalogram (EEG), electro-oculogram (EOG), submental electromyogram (EMG), oro-nasal airflow (by thermistors or thermocouples) and thoraco-abdominal movements (by respiratory belt), snoring intensity (by dB meter), pulse oximetry and leg movements.

(*Id.* at col. 6, l. 63, through col. 7, l. 3.)

18. Goor discloses that, "[i]in addition to the obstructive sleep apnea syndrome which results in frank cessations of breathing, there are additional obstructive sleep disordered breathing conditions recognized in the medical literature. These conditions are called hypopnea and upper airway resistance syndrome (UARS), respectively" (*id.* at col. 7, ll. 18-23).

PRINCIPLES OF LAW

As the Supreme Court pointed out in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), when determining whether the prior art supplied a reason for practicing the claimed subject matter, the analysis "need not seek

out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418; *see also id.* at 421 ("A person of ordinary skill is . . . a person of ordinary creativity, not an automaton.").

As to claim interpretation, "[u]nless the steps of a method actually recite an order, the steps are not ordinarily construed to require one." *Interactive Gift Express, Inc. v. CompuServe Inc.*, 231 F.3d 859, 875 (Fed. Cir. 2000).

ANALYSIS

We have carefully considered all of Appellant's arguments, but are not persuaded that the evidence of record fails to support the Examiner's prima facie case of obviousness.

Claim 1 recites a method of treating functional somatic syndromes. To perform the method, the practitioner must determine whether a patient suffers from inspiratory airflow limitation during sleep. The practitioner must also identify the patient as having a functional somatic syndrome. The practitioner must also treat the patient with an upper airway stabilization technique that includes positive airway pressure therapy.

Goor discloses a method for diagnosing sleep apnea, which is one of the most common and serious sleep disorders (FF 14-18). Thornton discloses a method for treating sleep apnea through the use of a CPAP (continuous positive air pressure) device, which allows easier breathing (FF 9-13). Given these disclosures, we agree with the Examiner that Goor and Thornton teach claim 1's steps of determining whether a patient suffers from

inspiratory airflow limitation during sleep, and treating the patient with positive airway pressure therapy.

We agree with Appellant, however, that neither Thornton nor Goor identifies sleep apnea syndrome as a functional somatic syndrome, nor do those references explicitly identify any particular airway obstructive disorder as a functional somatic syndrome. We also agree with Appellant that, when viewed in context, the sections of the Specification describing Appellant's sleep disorder-treating embodiment do not show that an ordinary artisan would have considered obstructive airway sleep disorders like sleep apnea to necessarily be functional somatic syndromes (FF 5-8).

Nonetheless, as Appellant concedes, it was recognized in the art that chronic fatigue syndrome was a known functional somatic syndrome, and that symptoms of functional somatic syndromes included chronic fatigue as well as sleep-related problems such as sleep maintenance insomnia and unrefreshing sleep (FF 1-4). Thus, we agree with the Examiner that an ordinary artisan, aware of the fatigue- and sleep-related characteristics of functional somatic syndromes, would reasonably have inferred that at least some of the individuals suffering from sleep patterns disrupted by the inspiratory airflow limitations described in Thornton and Goor would also be identified as having a fatigue-related functional somatic syndrome, such as chronic fatigue syndrome, and the treatment of those individuals would meet the limitations of the claims on appeal.

Moreover, as noted above, unless they specifically require the steps to be performed in a particular order, process claims encompass any method that includes all the claimed steps. *See Interactive Gift Express v. CompuServe*, 231 F.3d at 875. In the instant case, claim 1 encompasses first

performing the step of identifying a patient as having a functional somatic syndrome, such as chronic fatigue syndrome, then determining whether the patient suffers from inspiratory airflow limitation during sleep, and then treating that patient with positive airway pressure therapy.

As discussed above, chronic fatigue syndrome is a disorder recognized in the art as a functional somatic syndrome, and art-recognized symptoms of functional somatic syndromes include chronic fatigue and sleep-related problems such as sleep maintenance insomnia and unrefreshing sleep (FF 1-4). Thus, we conclude that an ordinary artisan, having identified a patient as having chronic fatigue syndrome, or another functional somatic syndrome with symptoms such as chronic fatigue, sleep maintenance insomnia, and/or unrefreshing sleep, would have considered it obvious to determine whether that patient suffered from a sleep-disrupting inspiratory airflow limitation like the sleep apnea described in Thornton and Goor, and if appropriate, would have treated that patient with positive airway pressure, as recited in claim 1.

Accordingly, we agree with the Examiner that the evidence of record supports a conclusion that an ordinary artisan viewing Thornton and Goor would have considered a process with all of the steps recited in claim 1, including the step of identifying a patient as having a functional somatic syndrome, prima facie obvious.

We therefore affirm the Examiner's obviousness rejection of claim 1 over Thornton and Goor, as well as its dependent claims 5, 6, and 11, which were not argued separately. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Claim 12 recites a process with the same steps as claim 1, except that rather than identifying a patient as having a functional somatic syndrome,

claim 12 only requires the practitioner to identify "one or more symptoms of a functional somatic syndrome." As noted above, it was known in the art that such symptoms included chronic fatigue as well as sleep-related problems such as sleep maintenance insomnia and unrefreshing sleep (FF 1-3).

Given that Goor and Thornton would have advised an ordinary artisan that sleep apnea sufferers also suffered from disrupted sleep, we agree with the Examiner that an ordinary artisan prompted by Goor and Thornton to diagnose and treat sleep apnea would also have considered it obvious to identify at least one fatigue- or sleep-related symptom of a functional somatic syndrome in such patients, as required by claim 12. Accordingly, we also affirm the Examiner's obviousness rejection of claim 12 over Thornton and Goor, as well as its dependent claims 16 and 17, which were not argued separately. *See* 37 C.F.R. § 41.37(c)(1)(vii).

The Examiner rejected claims 8, 9, 19, and 20, all of which depend either from claim 1 or claim 12, as obvious over Thornton, Goor, and Kowallik (Ans. 10-11). The Examiner concluded that, while the claimed steps of categorizing a patient as having upper airway resistance syndrome (UARS) or obstructive sleep apnea/hypopnea (OSA/H) were not described in Thornton or Goor, those steps would nonetheless have been obvious to an ordinary artisan in view of Kowallik's teachings of applying those criteria to categorize patients suffering from respiratory disorders (*id.*).

Appellant directs no specific argument to this rejection. Accordingly, as Appellant points to no deficiency in the Examiner's prima facie case, and we detect none, we affirm the Examiner's obviousness rejection of claims 8, 9, 19, and 20 over Thornton, Goor, and Kowallik.

The Examiner also rejected claim 10 as obvious over Thornton, Goor, and Bennett (Ans. 12). The Examiner concluded that, while the claimed step of observing alpha-delta sleep of a patient was not described in Thornton or Goor, that step would nonetheless have been obvious to an ordinary artisan in view of Bennett's teaching of applying that diagnostic method in diagnosis of functional somatic syndromes (*id.*).

Appellant directs no specific argument to this rejection. Accordingly, as Appellant points to no deficiency in the Examiner's prima facie case, and we detect none, we affirm the Examiner's obviousness rejection of claim 10 over Thornton, Goor, and Bennett.

SUMMARY

We affirm the Examiner's rejection of claims 1, 5, 6, 11, 12, 16, and 17 under 35 U.S.C. § 103(a) as obvious over Thornton and Goor.

We also affirm the Examiner's obviousness rejection of claims 8, 9, 19, and 20 over Thornton, Goor, and Kowallik.

We also affirm the Examiner's obviousness rejection of claim 10 over Thornton, Goor, and Bennett.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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